WILLKIE FARR & GALLAGHER LLP

April 30, 2025

VIA ECF

Honorable Ann M. Donnelly
United States District Court, Eastern District of New York
225 Cadman Plaza East, Courtroom 4GN
Brooklyn, New York 11201

RE: *U.S. ex rel. Olymbios v. CareDx, Inc., et al.*, No. 1:21-cv-00774

Dear Judge Donnelly:

On behalf of CareDx, Inc. ("CareDx"), Peter Maag, Reginald Seeto, Shamik Dholakia, and Sasha King (together, "Defendants"), we write pursuant to Rule 4(A) of the Court's Individual Rules to request a pre-motion conference on Defendants' anticipated motion(s) to dismiss Relator Michael Olymbios' ("Relator") amended complaint (ECF No. 42-1) in this government-declined qui tam action.

Background and Allegations[1]

CareDx provides diagnostic testing services that are designed to detect if a transplanted organ is being "rejected" by a transplant patient's body. Transplant patients face a lifelong risk of their organ being rejected, which can cause serious health complications including death. A core component of CareDx's testing services business is AlloSure Kidney, a novel blood test widely relied on by doctors to detect rejection of transplanted kidneys without an invasive biopsy. In 2017, the Centers for Medicare and Medicaid Services ("CMS") granted coverage through a "Local Coverage Determination" ("LCD") for AlloSure Kidney when it is used for cause, i.e., to confirm rejection where another clinical indicator was present, and for surveillance, i.e., to detect and prevent organ rejection before other clinical indicators materialize.

Olymbios is a former employee who left CareDx in October 2020 for its principal competitor, Natera, taking with him thousands of competitively sensitive documents as well as privileged material pertaining to CareDx's then-ongoing litigation against Natera. After CareDx demanded the return of these materials, Olymbios threatened to report CareDx to the Department of Justice. When CareDx did not back down, Olymbios filed this qui tam action under seal on February 12, 2021, triggering a confidential government investigation. (ECF No. 1.) The crux of the original complaint was that CareDx defrauded Medicare by billing for surveillance testing, which Olymbios alleged was not covered by the relevant LCD. The original complaint also alleged that CareDx violated the False Claims Act ("FCA") by paying illegal kickbacks to physicians.

[1] Defendants assume the truth of Relator's allegations only for purposes of this letter and reserve the right to dispute them.

While Relator's complaint remained under seal, an individual with access to a pre-filed version of the complaint sent an anonymous email using an encryption service to the incoming and outgoing presidents of a prominent association of transplant clinicians accusing CareDx of fraud and urging the organization to no longer promote CareDx's testing services. **The email included a copy of the sealed complaint, to which only Relator or his counsel would have had access, and the two recipients were on a list of "key opinion leaders" that Relator took from CareDx**. An individual also used the same or similar email addresses to send similar messages attaching another complaint against CareDx to another leading transplant doctor as well as the Medicare contractors charged with overseeing coverage for CareDx's testing. CareDx alerted the DOJ to these communications, and requested in writing at least three times that Olymbios deny or confirm any involvement, which he has repeatedly declined to do.

After exhaustively investigating Relator's allegations, the federal government declined to intervene in this action on July 12, 2024. (ECF No. 15.) On October 7, 2024, the Court ordered that the complaint be unsealed. (ECF No. 21.) Relator filed the Amended Complaint on April 1, 2025. (ECF No. 42-1.)[2] The Amended Complaint abandons the allegation that surveillance testing was not covered by the LCD. Instead, it focuses solely on the theory that CareDx paid kickbacks to providers in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and therefore caused the submission of false claims for payment of AlloSure tests in violation of the FCA, 31 U.S.C. §§ 3729 *et seq.*

Motion to Dismiss

Defendants plan to move to dismiss the Amended Complaint in its entirety.[3]

The Improper Disclosure of the Sealed Qui Tam Complaint Mandates Dismissal

There is no doubt that Relator improperly disclosed the sealed qui tam complaint. As courts in the Second Circuit have held, "[a] failure to abide by [the sealing] procedure is typically fatal and requires dismissal of the complaint with prejudice." *James v. Well Life Network Inc.*, 2023 WL 3997264, at *2 (E.D.N.Y. June 14, 2023). Numerous courts have dismissed qui tam actions because of violations of the sealing requirement. *See, e.g., U.S. ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995, 999 (2d Cir. 1995); *U.S. ex rel. Lyon v. Am. Med. Response*, 2011 WL 13377407, at *3-4 (E.D.N.Y. Jan. 19, 2011) (collecting cases). This is especially so where the relator has acted in bad faith, as Relator did here.

The Complaint Fails to Allege With Particularity the Submission of Any False Claims

The Amended Complaint should be dismissed because it fails to state a claim under the FCA. The FCA imposes liability upon a person who "knowingly" presents a "false claim" for payment, or who "knowingly" makes a "false record or statement material to a false or fraudulent claim." 31 U.S.C. §§ 3729(a)(1)(A) & (B); *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 152 n.3 (2d Cir. 2024). FCA claims, including allegations about an underlying fraud scheme and the submission of false claims,

[2] The Amended Complaint was filed under seal on April 1, 2025 (ECF No. 42-1) and unsealed on April 8, 2025 (ECF No. 51).

[3] While Defendants expect their motion(s) will be based upon the deficiencies set forth herein, Defendants reserve all rights, including but not limited to removing any grounds for the motion set forth herein or adding additional grounds. Defendants also note that a federal district court recently held that the qui tam provision of the FCA is unconstitutional and dismissed the underlying qui tam suit because the relator lacked standing under the FCA, and the issue is currently on appeal. *See U.S. ex rel. Zafirov v. Florida Medical Associates, LLC*, No. 8:19-CV-01236-KKM-SFP, 2024 WL 4349242 (M.D. Fla. Sept. 30, 2024), *appeal docketed*, No. 24-13581 (11th Cir. Oct. 30, 2024). Defendants reserve the right to challenge Relator's standing on this basis should the Second Circuit or U.S. Supreme Court so rule.

must satisfy the heightened pleading requirements of Rule 9(b). *U.S. ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 83 (2d Cir. 2017).

The Amended Complaint fails to meet this standard. It does not identify *any* claims actually submitted, much less any details about those claims. Moreover, Relator has not set forth a single allegation that Medicare reversed even one claim submitted by CareDx. This collapses Relator's FCA theory, which requires that CareDx submitted false claims *and* did so knowingly. Relator's false certification theory also necessarily fails.

Further, the government's continued reimbursement of AlloSure precludes Relator from demonstrating "materiality" under the FCA. *See Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 195 (2016) (when the government pays a particular claim "despite its actual knowledge that certain requirements were violated, [it] is very strong evidence that those requirements are not material."). CMS largely knew about the matters alleged—including that CareDx was submitting claims for testing conducted in connection with a mobile phlebotomy service launched during the pandemic (RemoTraC)—and the government continued paying these claims.

Relator's Anti-Kickback Statute Theory Fails to State a Viable FCA Claim

To plead an FCA violation premised on a violation of the AKS, Relator must "plead both the FCA violation and the underlying kickback scheme in compliance with Rule 9(b)." *See United States v. Novartis Pharms. Corp.*, 2020 WL 1436706, at *3 (S.D.N.Y. Mar. 24, 2020). By its own terms, the AKS creates FCA liability only for claims "resulting from" a violation of the AKS. 42 U.S.C. § 1320a-7b(g). This requires that Relator plead with particularity the link between the alleged kickback and specific false claims. *See, e.g., U.S. ex rel. Mooney v. Americare, Inc.*, 2013 WL 1346022, at *3-4 (E.D.N.Y. Apr. 3, 2013). Relator fails to meet this standard.

First, the Amended Complaint does not identify any claim that resulted from a supposed kickback scheme. Second, Relator fails to sufficiently allege that the purported schemes constitute "remuneration" under the AKS. *See* 42 U.S.C. § 1320a-7b(b)(1), (b)(2)(A). Relator does not allege with particularity that the kickbacks were (1) in fact provided to physicians; (2) exceeded fair market payments for bona fide services performed; or (3) not *de minimis* or otherwise covered by a safe harbor.[4]

Motion to Dismiss Briefing Schedule

Accordingly, Defendants respectfully request that this Court hold a pre-motion conference and establish a briefing schedule for Defendants' motion(s) pursuant to Rule 12(b)(6).[5] To the extent the Court is inclined to forgo a pre-motion conference, Defendants propose the following briefing schedule:

- Defendants' Motion(s) to Dismiss: June 30, 2025
- Relator's Opposition to Motion(s) to Dismiss: August 14, 2025
- Defendants' Reply In Further Support of Motion(s) to Dismiss: September 12, 2025

We thank the Court for its time and attention to this matter.

[4] *See, e.g.*, *OIG Message from leadership on minimizing burdens on providers* (Mar. 30, 2020), providing additional safe harbors for AKS liability during the COVID pandemic when CareDx was operating RemoTraC.

[5] Defendants are working together to coordinate efforts, including evaluating whether a joint motion to dismiss is appropriate. To the extent that Defendants file separate motions, they will seek to streamline briefing as much as possible.

April 30, 2025

Respectfully Submitted,

/s/ Nicholas H. Reddick
Nicholas H. Reddick